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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,905	09/04/2007	Jean-Francois Zagury	ZAGURY8A	5704

1444 7590 12/29/2009

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
EMCH, GREGORY S	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
12/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,905	ZAGURY, JEAN-FRANCOIS	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-14,17,18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) *4-8,18,20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,10-14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/08/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claims 1, 12, 14, 17, and 21 have been amended and claims 2 and 15 have been canceled as requested in the amendment filed on 14 December 2009. Following the amendment, claims 1, 3-8, 10-14, 17, 18, 20 and 21 are pending in the instant application.

Election/Restrictions

Applicant's election without traverse of Group II, claims 1, 3, 10-14 and 17, in the reply filed on 14 December 2009 is acknowledged.

Claims 4-8, 18, 20 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 14 December 2009.

Claims 1, 3, 10-14 and 17 are under examination in the instant office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 08 June 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claim 1 is objected to because of the following informalities: the claim recites residue numbers in the text. See 37 CFR 1.821-1.822. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 10-13 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims, as written, do not sufficiently distinguish the claimed invention over proteins that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). It is noted that the term "pharmaceutical composition" in claim 17 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481

(CCPA 1951). The claims should be amended to indicate the hand of the inventor by insertion of "isolated" or "purified," for example and by adding a pharmaceutically acceptable excipient to claim 17 (supported by the instant specification at e.g. paragraph [0047]). See MPEP 2105.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 12, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 10-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Rathjen et al. (US Patent no. 5,795,859, issued 18 August 1998).

Rathjen et al. teach a 26 amino acid peptide originating from mammalian TNFα, which comprises an amino acid sequence with 100% homology to SEQ ID NO: 5 (see sequence alignment, below), thus meeting the limitations of claims 1, 3 and 11. The patent teaches derivatives of the peptides of the invention (col.6, lines 7-18), thus meeting the limitations of claim 10. The patent teaches cyclization of the peptide as well as using D-amino acids (col.3, lines 7-8; col.4, line 35), thus meeting the limitations of claim 12. Pharmaceutical compositions comprising the peptides of the invention and pharmaceutically acceptable carriers are disclosed at col.4, lines 38-43), thus meeting the limitations of claim 17.

Although the patent does not explicitly recite the limitations of claim 13, i.e. characterized in that..., these are properties inherent to the peptide. Since the patent teaches the structural limitations of claim 13, the claim is anticipated. That is, the recitation of “has more than 80% sequence homology” in independent claim 1 is open claim language. Thus, claim 1 is open, and is not limited to the sequences (or 80% variants) of SEQ ID NO: 5. "Has" is generally considered open claim language (see MPEP 2111.03, section entitled Other Transition Phrases) which does not exclude additional unrecited elements, such as the remaining amino acids of Rathjen's protein. It is noted that if claim 1 was amended to e.g. "consists of a sequence more than 80% identical to one of the following...", such would be considered closed language. Then, claim 13 could be amended to e.g. ”An immunogenic compound comprising: a)

protein consisting of a peptide according to claim 1, and b) a heterologous carrier protein that increases the immunogenicity of the peptide in a) . Support for such a claim can be found at e.g. p.6, paragraph [0024] of the specification.

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US-08-178-268-47
; Sequence 47, Application US/08178268
; Patent No. 5795859
;  GENERAL INFORMATION:
;    APPLICANT:  RATHGEN, Deborah A
;    APPLICANT:  WIDMER, Fred
;    APPLICANT:  GRIGG, Geoffrey W
;    APPLICANT:  MACK, Philip O
;    TITLE OF INVENTION:  Peptide which Abrogates TNF and/or LPS Toxicity
;    NUMBER OF SEQUENCES:  47
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Nixon & Vanderhye P.C.
;      STREET:  1100 No. 5795859th Glebe Road, 8th Floor
;      CITY:  Arlington
;      STATE:  Virginia
;      COUNTRY:  USA
;      ZIP:  22201-4714
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  Floppy disk
;      COMPUTER:  IBM PC compatible
;      OPERATING SYSTEM:  PC-DOS/MS-DOS
;      SOFTWARE:  PatentIn Release #1.24
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/178,268
;      FILING DATE:  05-JAN-1994
;      CLASSIFICATION:  530
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  MITCHARD, Leonard C
;      REGISTRATION NUMBER:  29,009
;      REFERENCE/DOCKET NUMBER:  47-45
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  (703) 816-4000
;      TELEFAX:  (703) 816-4100
;  INFORMATION FOR SEQ ID NO:  47:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  26 amino acids
;      TYPE:  amino acid
;      STRANDEDNESS:  single
;      TOPOLOGY:  both
;    MOLECULE TYPE:  peptide
US-08-178-268-47

  Query Match             100.0%;  Score 64;  DB 1;  Length 26;
  Best Local Similarity   100.0%;
  Matches   12;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 DYLDFAESGQVY 12
              ||||||||||||
Db          9 DYLDFAESGQVY 20
```

Claims 1, 3, 10, 13, 14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Jensen et al. (WO 98/46642, published 22 October 1998).

Jensen et al. teach peptides originating from mammalian TNFα, including one which comprises an amino acid sequence with 100% homology to SEQ ID NO: 5 (see e.g, Jensen's SEQ ID NO: 4), thus meeting the limitations of claims 1 and 3. The reference teaches derivatives of the peptides of the invention (see p.24, lines 1-4, Examples), thus meeting the limitations of claim 10. Although the patent does not explicitly recite the limitations of claim 13, i.e. characterized in that..., these are properties inherent to the peptide. Since the patent teaches the structural limitations of claim 13, the claim is anticipated. See above discussion for the Rathjen et al. reference. The patent teaches that the TNF peptides of the invention are used as immunizing compositions for producing antibodies when administered to a subject in need thereof, said compositions comprising the peptides and an adjuvant (entire document; e.g. p.24, line 28 – p.25, line 2, p.28, lines 14-17), thus meeting the limitations of claim 14. Pharmaceutical compositions comprising the peptides of the invention and pharmaceutically acceptable carriers are disclosed at e.g. p.27, line 4 - p.29, line 2, thus meeting the limitations of claim 17.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached at (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G.E./

Gregory S. Emch
Patent Examiner
Art Unit 1649
20 December 2009

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
December 21, 2009